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**Re: Patent Office Filing for  
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PTO/SB/21 (05-03)

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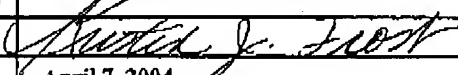
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<b>TRANSMITTAL FORM</b>  (to be used for all correspondence after initial filing)	Application Number	10/700,107	
	Filing Date	November 3, 2003	
	First Named Inventor	Schwendeman, et al.	
	Art Unit	1615	
	Examiner Name	Not yet assigned	
Total Number of Pages in This Submission	4	Attorney Docket Number	22727/04196

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Debra L. Hale

PATENT

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:  
Schwendeman, et al.

Serial No.: 10/700,107

Filed: November 3, 2003

For: **METHODS FOR STABILIZING  
BIOLOGICALLY ACTIVE AGENTS  
ENCAPSULATED IN  
BIODEGRADABLE CONTROLLED-  
RELEASE POLYMERS**

Examiner: Not yet assigned

Art Unit: 1615

Attorney Docket No.: 22727/04196

Commissioner for Patents  
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INFORMATION DISCLOSURE STATEMENT

Dear Sir:

The information cited on the accompanying form PTO-1449 was cited in the parent application and is also hereby submitted in compliance with 37 CFR §§1.56, 1.97 and 1.98 for consideration by the Examiner in connection with this application.

Respectfully submitted,

Date: April 7, 2004By: Kristin J. Frost

Kristin J. Frost, Reg. No. 50,627  
(216) 622-8895

<b>Subst. Form PTO-1449</b>  <b>APPLICANT'S INFORMATION DISCLOSURE STATEMENT</b>	<b>Atty. Docket No.:</b> 22727/04196	<b>Serial No.:</b> 10/700,107
	<b>Applicant:</b> Schwendeman, et al.	
	<b>Filing Date:</b> November 3, 2003	<b>Group:</b> 1615

## U.S. PATENT DOCUMENTS

Initial*	Document No.	Date	Name	Class	Subcl.	Filing Date
	5,413,797	May 9, 1995	Khan, et al.			Jun. 30, 1994
	5,643,605	July, 1997	Cleland, et al.	424/489		
	5,654,010	August 5, 1997	Johnson, et al.			Jun. 7, 1995
	5,656,297	August 12, 1997	Bernstein, et al.			May 3, 1994
	5,912,015	June 15, 1999	Bernstein, et al.			Apr. 7, 1998

## FOREIGN PATENT DOCUMENTS

	Document No.	Date	Country	Class	Subcl.	Translation ?

## OTHER PRIOR ART

	"Stabilization of tetanus and diphtheria toxoids against moisture-induced aggregation" by Schwendeman, et al., <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 92, pp. 11234-11238, November 1995.
	"Stabilization of Proteins Encapsulated in Cylindrical Poly(lactide-co-glycolide) Implants: Mechanism of Stabilization by Basic Additives" by Zhu, et al., <u>Pharmaceutical Research</u> , Vol. 17, No. 3, 2000, pp. 350-356.
	"Stabilization of Vinca Alkaloids Encapsulated in Poly(lactide-co-glycolide) Microspheres" by Marinina, et al., <u>Pharmaceutical Research</u> , Vol. 17, No. 6, 2000, pp. 677-682.
	Chapter 48 "Gastric Antacids and Digestants" by Harvey, <u>The Pharmacological Basis of Therapeutics, Fourth Edition</u> , The McMillan Company, London, Toronto.
	"The stability and immunogenicity of a protein antigen encapsulated in biodegradable microparticles based on blends of lactide polymers and polyethylene glycol" by Lavelle, et al., <u>Vaccine</u> , 17, pp. 512-529, 1999.
	"Buffers for pH and Metal Ion Control" by D.D. Perrin, et al., <u>Buffers for pH and Metal Ion Control</u> , Appendix III, p. 160; Appendix II, pp. 138-139, Chapman and Hall, London, New York, 1974.
	"Biochemistry" by D. Voet, et al., <u>Biochemistry</u> , Chap. 2. Aqueous Solutions, p. 37, John Wiley & Sons, New York, Chichester, Brisbane, Toronto, Singapore, 1990.
	"Buffer Solutions Operational Definitions of pH" by R.A. Robinson, <u>CRC Handbook of Chemistry and Physics</u> , 70th Ed., p. D-144, CRC Press, Inc., Boca Raton, FL, 1989-90.
	<u>The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals</u> , 11th Ed., pp. 1366, ?, 256, 1600, MISC-113, Merck & Co., Inc., Rahway, NJ, 1989.

Examiner:

Date Considered:

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